MINUTES
USP CHAPTER 800 TASK FORCE MEETING
August 8, 2017

CALL TO ORDER: The first meeting of the USP Chapter 800 Task Force was held at the Seelbach Hotel Ballroom, 500 South 4th Street, Louisville, Kentucky. Katie Busroe, Chair, called the meeting to order at 1 pm EST.

Members present: Katie Busroe, Chair; Jeff Akers, ARH; Ann Albrecht, Lexington Clinic Pharmacy; Holly Byrnes, KSHP President-elect; John Carver, Baptist Health; Gina Guarino, Kroger; Amanda Harding; Kentucky Board of Pharmacy staff; Chris Harlow, KPhA President; Stephanie Huff, University of Louisville Hospital; Daniel Jones, Strawberry Hills Pharmacy; Barb Jolly, Sullivan University College of Pharmacy; Leslie Kenney, KSHP President; Matt Martin, PCCA; Trenika Mitchell, University of Kentucky College of Pharmacy; Anne Marie Megibben, Compound Care Pharmacy; Chris Palutis, C&C Pharmacy; Adam Parrish, Walmart; Ron Poole, Kentucky Board of Pharmacy Board Member; Phillip Schwieterman, University of Kentucky Hospital; Kent Shelton, Lexington Compounding; Robin Walters, Pikeville Medical Center Oncology Infusion Center Pharmacy; Brian Yarberry, Norton Children's Hospital; and Ex-Officio members: Mark Glaser, KPhA Executive Director; and Anne Policastri, KSHP Executive Vice President. Task force members Seth Depasquale, BET Pharmacy; Michelle DeLuca Fraley, Ephraim McDowell Cancer Support Clinic; and Joel Thornbury, Nova Pharmacy were unable to attend.

There were approximately 75 guests present.

DISCUSSION: At the July 12, 2017, Kentucky Board of Pharmacy Board Meeting, the Kentucky Board of Pharmacy charged this Task Force to make a recommendation to the Board regarding USP Chapter 800, Hazardous Drugs – Handling in Healthcare Settings. Several options for a recommendation were discussed, including but not limited to: adoption of USP Chapter 800, adoption of parts of USP Chapter 800 and no adoption of USP Chapter 800. Chair Busroe will summarize the options to present at the next Task Force Meeting.

NEXT MEETING: The next USP Chapter 800 Task Force Meeting will be September 12, 2017, from 1 pm to 3 pm EST, at a site to be determined.

ADJORNMENT: On motion by Matt Martin, seconded by Ron Poole, and passed unanimously, the meeting adjourned at 3 pm EST.

Respectfully submitted,
Katie Busroe, Chair

AGENDA USP CHAPTER 800 TASK FORCE
Seelbach Hotel Ballroom
500 South 4th Street
Louisville, KY
August 8, 2017

I. Call to order
II. Introductions
III. Discussion USP Chapter 800
- **a.** Other states
- **b.** Commercially available products
- **c.** Nonsterile compounding
  - **i.** APIs and antineoplastic drugs
  - **ii.** Non-antineoplastic drugs and reproductive hazard drugs
- **d.** Sterile compounding
  - **i.** APIs and antineoplastic drugs
  - **ii.** Non-antineoplastic drugs and reproductive hazard drugs

IV. Next meeting

GENERAL GOVERNMENT CABINET

Kentucky Board of Pharmacy

(Amendment)

201 KAR 2:076. [~~Parenteral pharmaceutical~~] Compounding.

RELATES TO: KRS 217.055(2), 217.065(7), [~~218A.010(13)(a)~~], 315.020(1), 315.035(6), 315.0351, 315.191(1)(a), (g)

STATUTORY AUTHORITY: KRS 315.020(1), (2), 315.035(6), 315.0351, [~~315.065(1), (2),~~] 315.191(1)(a), (g)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy is responsible to insure minimum standards of practice of [~~parenteral~~] compounding by pharmacies and pharmacists. The board is also responsible to insure the safety of all products provided to the citizens of the Commonwealth. This administrative regulation establishes the requirements for compounding non-sterile and sterile preparations.

Section 1. (1) A policy and procedure manual for non-sterile and sterile [~~parenteral pharmaceutical~~] compounding shall be readily available at a pharmacy for inspection purposes.

(2) A copy of the manual shall be made available to the board upon request. [~~The manual shall include policies and procedures for:~~

~~(1) Oncology drugs;~~

~~(2) Disposal of unused supplies and medications;~~

~~(3) Drug destruction and return;~~

~~(4) Drug dispensing;~~

~~(5) Drug labeling;~~

~~(6) Storage;~~

~~(7) Duties and qualifications for staff;~~

~~(8) Equipment;~~

~~(9) Handling of hazardous wastes;~~

~~(10) Investigation drug protocol;~~

~~(11) Safety;~~

~~(12) Recordkeeping;~~

~~(13) Reference material;~~

~~(14) Sanitation;~~

~~(15) Security~~

~~(16) Transportation; and~~

~~(17) Quality assurance, as relates to:~~

~~(a) Recall procedures;~~

~~(b) Storage and dating;~~

~~(c) Educational procedures for staff and patient;~~

~~(d) Sterile procedures, to include routine maintenance and hood certification; and, if necessary,~~

~~(e) Sterile testing of end products, operator procedures, and environment.~~]

(3) The manual shall be reviewed and revised on an annual basis.

Section 2. (1) Effective January 1, 2018, all non-sterile compounded preparations shall be compounded pursuant to United States Pharmacopeia (USP) 795, unless specified portions submitted by a pharmacist have been waived by the Board.

(2) Effective January 1, 2018, all sterile compounded preparations shall be compounded pursuant to USP 797, unless specified portions submitted by a pharmacist have been waived by the Board.

(3) After January 1, 2018, all written waiver requests submitted by a pharmacist shall be considered by the Board at its next regularly scheduled meeting.

(4) The board, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirement of any specified portion of USP 795 or 797. [~~The following physical requirements are in addition to other requirements set forth in KRS 217.055 and 315:020:~~

~~(1) The licensed pharmacy shall have a designated area for preparing compounded parenteral pharmaceuticals. This area shall be designed to withstand routine disinfecting procedures and shall be kept free of particulate generators, e.g., corrugated cardboard containers. This area shall be designed to avoid unnecessary traffic and airflow disturbances. It shall be used only for the preparation of sterile products. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.~~

~~(2) The minimum equipment shall be:~~

~~(a) Laminar airflow hood or Class 100 clean room;~~

~~(b) Sink with hot and cold running water which is convenient to the compounding area;~~

~~(c) Appropriate disposal containers for used needles, syringes, and if applicable, cytotoxic and hazardous wastes from preparation of said agents;~~

~~(d) A Class II vertical flow biological safety cabinet, if oncology agents are prepared;~~

~~(e) Refrigerator or freezer with a thermometer; and~~

~~(f) A temperature controlled delivery container (not required if delivered in the same facility).~~

~~(3) The minimum supplies shall be:~~

~~(a) Disposable needles, syringes, and other supplies needed for aseptic parenteral compounding;~~

~~(b) Disinfectant cleaning solutions;~~

~~(c) Hand-washing agent with bactericidal action;~~

~~(d) Disposable, lint-free towels or equivalent;~~

~~(e) Appropriate filters and filtration equipment;~~

~~(f) Oncology drug spill kit; and~~

~~(g) Disposable gowns, and sterile disposable gloves.~~

~~(4) This area of the pharmacy shall not be accessible to the public and no one shall have access without supervision of the pharmacist.~~

~~(5) The pharmacy shall have current reference materials related to sterile products.~~]

Section 3. (1) A facility that compounds non-sterile or sterile preparations [~~Each licensed pharmacy~~] shall be managed by a pharmacist-in-charge (PIC) [~~pharmacist~~] licensed to practice pharmacy in the Commonwealth and who is knowledgeable in the specialized functions of preparing and dispensing compounded non-sterile and[~~,~~] sterile preparations [~~pharmaceuticals~~], including the principles of aseptic technique and quality assurance.

(2) The PIC [~~pharmacist in charge~~] shall be responsible for the: purchasing, storage, compounding, repackaging, dispensing, [~~and~~] distribution of all drugs and preparations, [~~pharmaceuticals. The pharmacist shall also be responsible for the~~] development and continuing review of all policies and procedures, training manuals, [~~and the~~] quality assurance programs, and [~~as well as~~] participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness.

(3) The PIC [~~pharmacist in charge~~] may be assisted by additional pharmacy personnel adequately trained, to the satisfaction of the PIC, in this area of practice and for each product they will be compounding. [~~A pharmacist shall be accessible at all times at each licensed facility to respond to patients' and other health professionals' questions and needs.~~]

Section 4. (1) The pharmacist shall receive a written, electronic, facsimile, or verbal prescription, or medical [~~direct copy~~] order from a prescriber before dispensing any compounded, non-sterile or sterile preparation [~~parenteral product~~]. These prescriptions or medical [~~direct copy~~] orders shall contain the following:

(a) Patient's name, and species if not human;

(b) Patient's address on controlled substances prescriptions or location (room number);

(c) Drug name and strength;

(d) Directions for use;

(e) Date;

(f) Authorized prescriber's name;

(g) Prescriber's address and DEA number, if applicable;

(h) Refill or end date instructions, if applicable; and

(i) Dispensing quantity, if applicable.

(2) A pharmacy generated patient profile shall be maintained separate from the prescription file. The patient profile shall be maintained under the control of the PIC [~~pharmacist in charge~~] for a period of two (2) years following the last dispensing activity. In addition, a medication administration record (MAR) as part of the institutional [~~medical~~] record shall be retained for a period of five (5) years from date of the patient's discharge from the facility, or in the case of a

minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longer. Supplemental records may also be employed as necessary. The patient profile shall contain:

(a) Patient's name;

(b) Name of compounded preparation [~~Sterile product~~] dispensed;

(c) Date dispensed;

(d) Drug content and quantity; and

(e) Patient's directions.

(3) Each compounded preparation [~~sterile pharmaceutical~~] dispensed to patients shall be labeled with the following information:

(a) Name, address, and telephone number of the licensed pharmacy, if product will leave the premises;

(b) Date;

(c) Identifying number;

(d) Patient's full name;

(e) Name of each drug, strength, and amount;

(f) Directions for use, including infusion rate;

(g) Required controlled substances transfer warnings, where applicable;

(h) Beyond use [~~Expiration~~] date;

(i) Identity of dispensing pharmacist;

(j) Storage requirements, when applicable; and

(k) Auxiliary labels, when applicable.

(4) The PIC [~~pharmacist in charge~~] shall maintain access to and submit, as appropriate, such records and reports as are required to insure the patient's health, safety, and welfare. Records shall

be readily available, maintained for two (2) years at a facility not computerized, but for five (5) years at a facility utilizing computerized recordkeeping, and subject to inspection by the Board of Pharmacy or its agents. These shall include the following:

(a) Patient profile;

(b) Purchase records;

(c) Biennial controlled substances inventories;

(d) Policy and procedures manual;

(e) Policies and procedures for hazardous [~~cytotoxic~~] wastes, if applicable;

(f) Quality assurance records; and

(g) Such other records and reports as may be required by law and rules and administrative regulations of the Kentucky Board of Pharmacy.

(5) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's records. Release of this information shall be in accordance with federal and state laws.

(6) [~~(5)~~] The PIC [~~pharmacist in charge~~] shall be responsible for the environmental control of all products shipped. Any compounded[~~,~~] product [~~sterile pharmaceutical~~] that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product leaves the premises.

(7) [~~(6)~~] The PIC [~~pharmacist in charge~~] shall be responsible for assuring that there is a system for the disposal of hazardous waste in a manner that does not endanger the public health.

~~(7) A quality assurance program documented by the pharmacist shall be available to provide accountability for the manufacturing and distribution of sterile parenteral products.~~

Section 5. Hazardous Drugs. (1) Effective January 1, 2018, all non-sterile preparations that contain hazardous substances shall be compounded pursuant to USP Chapter 795.

(2) Effective January 1, 2018, all sterile compounded preparations that contain hazardous substances shall be compounded pursuant to Chapter 797.

[~~Licensed pharmacies that prepare oncology agents shall meet the following additional requirements in order to insure the protection of the personnel involved:~~

~~(1) All oncology agents shall be compounded in a vertical flow, Class II, biological safety cabinet, and other products may be compounded in this cabinet;~~

~~(2) Protective apparel shall be worn by personnel compounding oncology drugs, and this shall include disposable gloves and gowns;~~

~~(3) Proper aseptic and safety techniques shall be used by personnel compounding oncology agents;~~

~~(4) Appropriate disposable procedures for cytotoxic waste shall be developed that comply with applicable state and federal regulations;~~

~~(5) Written procedures for handling both major and minor spills of cytotoxic agents shall be developed; and~~

~~(6) Prepared doses of oncology drugs shall be dispensed, shipped, or delivered in a manner to minimize the risk of accidental rupture of the primary container and labeled with a distinctive cautionary label as being hazardous.~~

Section 6. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121. [~~There shall be a documented, ongoing quality control program that monitors personnel performance, equipment, and facilities. Quality assurance procedures, at a minimum, shall include:~~

~~(1) Recall procedures;~~

~~(2) Storage and dating;~~

~~(3) Educational procedures for staff;~~

~~(4) Sterile procedures;~~

~~(5) Hood or clean room annual certification by an independent contractor in accordance with federal standard 209B and NSF standard No. 49;~~

~~(6) Prefilter cleaning and replacement when appropriate;~~

~~(7) Justification of the chosen expiration dates for compounded parenteral products; and~~

~~(8) Documentation of quality assurance audits at regular, planned intervals, including infection control and sterile technique audits.~~]

Section 7. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) USP 795, Revision Bulletin, Official January 1, 2014; and

(b) USP 797, Revision Bulletin, Official June 1, 2008.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m.

_____

Scott Greenwell, R.Ph., President
Kentucky Board of Pharmacy

Date: _____

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on June 28, 2017, at 9:00 a.m. at the Board's office, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601. Individuals interested in attending this hearing shall notify this agency in writing by five workdays prior to this hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled.

This hearing is open to the public. Any person will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made.

If you do not wish to attend the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through June 30, 2017.

Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to: Steve Hart, Executive Director, Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601; Telephone No. (502) 564-7910; Facsimile No. (502) 696-3806; email: Steve.Hart@ky.gov

REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

201 KAR 2:076. Compounding.
Contact person: Steve Hart
Contact Phone No.: 502-564-7910
Contact email: steve.hart@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum standards of practice for compounding non-sterile, sterile, and hazardous preparations.

(b) The necessity of this administrative regulation: This regulation is necessary to ensure the safety of compounded products provided to the citizens of this Commonwealth.

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation establishes compounding requirements for pharmacies and pharmacists; the Board is authorized to promulgate administrative regulations pertaining to pharmacies and pharmacists.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Pharmacies and pharmacists will have notice of minimum standards for compounded preparations which are required to be promulgated by administrative regulation pursuant to KRS 13A.100(1).

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment establishes that compounded preparations shall be compounded pursuant to standards of United States Pharmacopeia (USP), which is already recognized by the Cabinet for Health and Family Services.

(b) The necessity of the amendment to this administrative regulation: The amendment establishes the standards under which compounded products shall be prepared.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment establishes: health and sanitation standards as authorized by KRS 315.035(6); duties of the pharmacist-in-charge, as required by KRS 315.020(1) and 315.0351(7), to be knowledgeable in the preparation of compounded products to ensure quality assurance; and standards pertaining to pharmacies and pharmacists, authorized by KRS 315.191(1)(a) and (g).

(d) How the amendment will assist in the effective administration of the statutes: The amendment establishes clear standards of practice for compounded preparations, that will serve to protect the public.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates approximately 1200 pharmacies will be affected by this regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacists and pharmacies will have to comply with USP standards that were established in 2004. USP standards are already recognized by the Cabinet for Health and Family Services and approximately 40 boards of pharmacy in the United States.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs to pharmacies that are in compliance with USP standards that have been in place since 2004.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with this regulation greatly insures patient safety.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No new costs will be incurred by the board.

(b) On a continuing basis: No new costs will be incurred by the board.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Enforcement of this regulation shall be accomplished through inspections. The Board of Pharmacy generates its own revenues without contribution by the General Assembly.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of the amendment to this regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering was not applied as the regulation is applicable to all that prepare compounded sterile, non-sterile or hazardous products.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation No. 201 KAR 2:076
Contact Person: Steve Hart
Contact Phone No.: 502-564-7910
Contact email: steve.hart@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a) and (g) authorize the Board to promulgate administrative regulations to regulate and control pharmacies and pharmacists. The Board may promulgate health and sanitation standards pursuant to KRS 315.035(6). KRS 315.020(1) and 315.0351(7) require a pharmacist-in-charge in all pharmacies.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None

(c) How much will it cost to administer this program for the first year? No additional cost for the agency, since enforcement of compounding is and has been a responsibility of inspectors.

(d) How much will it cost to administer this program for subsequent years? No additional cost for the agency, since enforcement of compounding is and has been a responsibility of inspectors.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

Summary of Material Incorporated by Reference

USP 795 is a 7-page document that provides compounders with guidance on good compounding practices for nonsterile compounded preparations.

USP 797 is a 61 page document that provides compounders with guidance on good compounding practices for sterile compounded preparations.